

particularity for one of ordinary skill in the art to understand the subject matter that is distinctly claimed in the present invention. Applicants assert that the description of a flow-through pen in the present specification is understood by one of ordinary skill in the art as being a wick-type nib pen applicator. It is not necessary for Applicants to describe this type of pen as it is well-known by one of ordinary skill in the art for at least 15 or more years. This is evidenced by the description of such a pen in the reference, U.S. Patent No. 4,761,277 dated August 2, 1988, cited by the Examiner. It is not necessary that the specification describe the claimed invention *ipsis verbis* to comply with the written description requirement. *In re Edwards*, 568 F.2d 1349, 196 USPQ 465 (CCPA 1978). Further, it is not necessary for a specification to describe that which is known in the art by one of ordinary skill in the art. *In re Myers*, 410 F.2d 420, 427 (C.C.P.A. 1969). Because one of ordinary skill in the art would understand the scope of the claims in light of the present specification, the present claims meet the requirements of §112, first paragraph and Applicants, therefore, respectfully request that this rejection be withdrawn.

Applicants previously maintained in their Response of February 18, 2003, that the term “long-wearing” is clear and concise. This was in response to the Examiner’s assertion that the term is not defined by a lower limit in the claims or the specification. However, it is inherent that the lower limit of a composition that is long-wearing is irrelevant. The issue is how long does it last, and therefore, the upper limit is the primarily salient parameter. In the case of the present invention, it lasts on the skin for up to a full day. There is no requirement under section §112 that dictates that a range having a maximum and a minimum value must be present. A single comprehensive value can be sufficient. What is reasonably known and understood by one of ordinary skill in the art upon reading the present specification is that the compositions of the present invention are “long-wearing” when the compositions are on the skin for up to a full day.

In addition, Applicants submit herewith 3 references containing cosmetic claims using the term known by one of ordinary skill in the art, “long-wearing.” In U.S. Patent Number 6,444,212, issued as recently as September 3, 2002 while the present application was repeatedly being objected to for the use of the very same term, “long-wearing” was allowed in the ‘212 claims while the ‘212 specification fails to provide a minimum or maximum value defining the term. In addition, Applicants submit two other examples of claims using the term “long-wearing”. In each example, there is no range, and more specifically, there is no upper or lower limit provided for the term “long-wearing”. Applicants point out that a definition in the ‘212 patent for the term long-wearing is not found. Thus, not only is there not a range, there is not even a single value, whether it be a maximum or a minimum value, set forth in any of the 3 patents submitted that contain claims using the term “long-wearing”. This is presumably because there is no such requirement under section 112. However, Applicants request that if such a requirement

does exist under section 112, that the basis of the requirement be more clearly identified and applied consistently as required by the MPEP 706 ("the standards of patentability applied in the examination of claims must be the same throughout the Office").

Another term found by the Examiner to be indefinite is the word "derived." The Examiner questions whether the claim refers to acrylic acid polymers or polymers derived from acrylic acid. It is not clear to Applicants how a polymer derived from acrylic acid is not an acrylic acid polymer. Therefore, the distinction apparently being made is not understood. As mentioned above, Applicants are not required to describe that which is known by one of ordinary skill in the art. Previously, Applicants demonstrated that one of ordinary skill in the art understands what the term derived means and in the context of the present claims it is understood that an acrylic acid polymer is synonymous with an acrylic acid derived polymer or a polymer derived from acrylic acid. Therefore, Applicants request further clarification as to why the present application is being rejected for use of this commonly used term in view of the fact that the very same term has been allowed in other instances.

II. Section 103 Issues

A. The '072 Reference

The Examiner's obviousness rejection centers on the '072 reference which, according to the Examiner, generally discloses organic pigments which includes water-soluble pigments. In the Advisory Action, the Examiner points out that D&C Yellow No. 5, disclosed in the '072 reference, is specifically recited in the present specification as being a preferred water-soluble pigment. However, Applicants assert that D&C Yellow No. 5 is available both as 1) a water soluble pigment, and as 2) a water insoluble pigment. The difference between the D&C Yellow No. 5 described in the '072 reference and the FD&C Yellow No. 5 disclosed in the present invention is rooted in the type of FD&C Yellow No. 5 described in each and the context of the type of pigments described in each. The present specification clearly sets forth that the pigments described therein are water soluble, unlike the '072 reference which describes water insoluble pigments. Thus, the '072 reference fails to teach or suggest the water soluble FD&C Yellow No. 5 of the present invention, and it therefore, fails to render the present invention obvious.

The present invention relates to long-wearing compositions comprising an acrylic or methacrylic acid derived polymeric or copolymeric component in combination with at least one water-soluble organic pigment. One of the water-soluble pigments described in the present invention is FD&C yellow No. 5. The composition is water resistant and does not run or settle into lines and creases on the skin. As the Examiner noted previously and in the present Advisory Action, FD&C yellow No. 5 is disclosed in the present invention as an example of the water soluble organic pigments, at page 4, line 14. Applicants

submit that the inclusion of FD&C yellow No. 5, is in the water soluble form as the sodium salt yellow solution in water, by virtue of specifying that the pigment is water soluble. Moreover, Applicants have previously argued and further support their argument herein that the '072 reference is specifically limited to water-insoluble pigments and that FD&C yellow No. 5 is taught in the '072 reference in its water insoluble form and not its water soluble form.

To further elaborate upon this point, Applicants submit the data sheets for FD&C yellow No. 5 and FD&C yellow No. 6 to demonstrate that these pigments are available in both water soluble and water insoluble forms. Applicants submit a reference entitled "Coloring of Food, Drugs, and Cosmetics", by Gisbert Otterstatter, pp. 148 – 51, 173 – 75 (1999) ("the Coloring Reference"). In the Coloring reference, for each C.I. 15985 and C.I. 19140, the pigment is described as being both 1) a sodium salt yellow-orange or yellow solution in water, referring to its water soluble form, and 2) a water insoluble aluminum lake yellow-orange or yellow powder, referring to its water insoluble form. Thus, FD&C yellow No. 5 can be either a water soluble pigment or a water insoluble pigment. The '072 reference, when read as a whole, teaches and/or suggests the water insoluble form of FD&C Yellow No. 5, by virtue of the specific description set forth in the '072 reference..

The Examiner finds that the mere mention of D&C Yellow No. 5 in the '072 reference includes the water soluble pigment even though the mention of D&C Yellow No. 5 is in the context of other particulate type pigments, and specifically describes organic lakes. This is not an accurate reflection of what one of ordinary skill in the art would interpret the term "FD&C Yellow No. 5" to be in the '072 reference upon review of the '072 reference as a whole. This is because FD&C Yellow No. 5 pigment can exist in both the soluble and the insoluble form of the pigment as described in the data sheet for C.I. 19140. This, Applicants believe, has led to the misunderstanding regarding the inclusion of the yellow water soluble organic pigment of the present invention, and that of the yellow water insoluble organic pigment in the '072 reference.

Because the context of the pigments in the '072 reference are water insoluble pigments, in general, and because the pigments are placed in a solid component of the '072 compositions, Applicants have repeatedly argued that the disclosure of organic pigments in the '072 reference is indeed specific to water-insoluble organic pigments, namely, the aluminum lake yellow powder that one of ordinary skill in the art would expect to find in the solid component of the '072 reference. The evidence that supports Applicants' assertion is found both in the prior art and in the '072 reference itself. First, the exact language of the '072 reference describing the water insoluble pigment is provided below, starting at column 5, line 64 for section D. Pigments.

The solids component of the mascara compositions of the present invention contain cosmetically acceptable pigments selected from the group consisting of inorganic pigments, organic pigments, and pearlescent pigments. . . . Pigments are selected from the group consisting of inorganic pigments, organic lake pigments, pearlescent pigments, and mixtures thereof. Said pigments may optionally be surface-treated within the scope of the present invention but are not limited to treatments such as silicones, perfluorinated compounds, lecithin, and amino acids.

The organic pigments and lakes useful in the present invention include those selected from the group consisting of . . . D&C Yellow No. 6 (CI 15,985), . . .

Thus, based on the '072 description of the pigments in the solid component, Applicants assert that this reference fails to teach or suggest the water-soluble pigment of the present invention for two reasons. First, the '072 pigments are part of a solid portion in the oil phase of the '072 emulsion compositions, as indicated above, at column 6, lines 7 to 9, of the '072 reference. The pigments are taught to include, *inter alia*, organic lake pigments which are water insoluble forms of the pigment. Further, the group of pigments described by the '072 reference includes other particulate (i.e., water insoluble) types of pigments, namely, inorganic pigments and pearlescent pigments. Both of these types of pigments are dispersed in water and are not water soluble. Therefore, reviewing the '072 reference as a whole, one of ordinary skill in the art would understand that the D&C Yellow No. 5 taught therein is a water insoluble pigment.

As explained in Applicants' response of June 15, 2000, organic lake pigments are solids and are not water soluble. In general, lakes are made by extending a salt on a substrate, and are insoluble pigments, like inorganic pigments. This definition is pursuant to 21 C.F.R. 82.51, previously submitted, wherein FD&C lakes are defined by their process of manufacture by combining a colorant with a basic radical aluminum or calcium. Therefore, lakes are particulate in nature, i.e., insoluble pigments, and are not the water soluble organic pigments of the present invention. In support of this, Applicants previously submitted a copy of a reference disclosing that organic lakes are not water soluble. FD&C Yellow No. 5 Aluminum Lake, for example, is described in the CTFA Monographs (6th Edition 1995) at p. 386 as an insoluble pigment. Thus, the '072 reference teaching of the water insoluble form of FD&C yellow No. 5, is not a teaching or suggestion of a water soluble organic pigment and fails to, therefore, render the present invention obvious.

Further evidence that the '072 pigments are water insoluble is found in the teaching that the pigments, in the solid component, are present in the oil phase of the '072 compositions. Reviewing the '072 reference as a whole, the organic pigments are only disclosed as being present in the oil phase of the '072 emulsion compositions. This is indicated by the processing directions starting at column 7, line 5. Therefore, assuming *arguendo* the organic pigments could be considered to be water soluble, the '072

reference fails to teach or suggest placing the organic lake pigments in the water phase of the '072 emulsion compositions. There is no teaching or suggestion in the '072 reference to arrange a specific combination of any pigment with an acrylic or methacrylic acid polymer in an aqueous based system, such as those described in the present invention. Therefore, Applicants maintain that the '072 reference fails to teach or suggest the water soluble pigments in the aqueous based compositions of the present invention. The mere teaching of elements without connecting them to achieve the beneficial results of the present invention fails to place the present invention in the possession of one of ordinary skill in the art. The present invention, namely, a combination of a methacrylic or acrylic acid polymer and a water soluble pigment in an aqueous system is not taught or suggested by the '072 reference.

The Examiner responds to this argument by asserting that compositions disclosed in the '072 specification do not require oil or wax nor do they require that the pigments be incorporated into an oil or wax phase, and by noting a couple of points. First, the Examiner notes that all disclosures in a patent must be evaluated, including non-preferred embodiments. Applicants have not found any teaching in the '072 reference of the pigments in any phase except the oil phase. Thus, Applicants request reference to where in the '072 reference, a non-preferred embodiment is taught such that the pigments in the solid component are placed anywhere else other than the oil phase. Second, the Examiner points out, with a reference to *In re Nehrenberg*, 126 USPQ 383 (CCPA 1960), that a disclosure of a composition of matter in a reference may be anticipatory even though the reference indicates that the composition the composition is not preferred or even unsatisfactory for the intended purpose. In response, Applicants note that the case in *Nehrenberg*, involved an express statement in the reference regarding the higher amount of carbon and the resulting effect on toughness of the steel in such a case. Therefore, the *Nehrenberg* case is unlike that of the present case where the '072 reference is silent as to where else the pigment in the solid component could be placed, and is similarly, silent as to how the pigment in the solid component would behave if it were placed any where other than in the oil phase. Therefore, Applicants maintain that the '072 reference fails to teach or suggest the compositions of the present invention where the water soluble pigments are combined with the polymeric component in the aqueous based system, and a *prima facie* case of obviousness is not made.

B. The '072 and the '277 References

The Examiner maintains that the '072 and the '277 references render Claims 1 to 21 obvious under 35 U.S.C. §103(a). Further, the Examiner notes that it appears that the two obviousness rejections have been coalesced. However, Applicants' previous statements jointly regarding these two rejections, does not mean, nor was it intended, that Applicants in any way coalesced these two arguments. It was

previously asserted that each of the references, alone and in combination, at page 2 of Applicants Response of July 9, 2002, fails to render the present invention obvious. To recap, the compositions of the present invention utilize a simple acrylic or methacrylic acid polymeric system that permits the beneficial use of water soluble pigments without the drawbacks of fading and running in an aqueous based system, as well as in the absence of the drawbacks associated with clogging.

In support of the obviousness rejection based on the combination of the cited references, the Examiner asserts that there is motivation to combine the '072 reference with the '277 reference based on providing a colored composition that can be easily applied to the eye area. Applicants responded that the combination proposed by the Examiner does not make the present invention because the pigments from each of the references are not interchangeable when considering the cited references as a whole, and therefore, they do not, alone or in combination, render the present invention obvious. The Examiner further finds that the claims of the present invention are not commensurate in scope with a limitation directed to clogging or a wick-type nib. However, Applicants disagree with this finding because in Claims 15 to 18 and in Claim 22, specific reference is made to the flow-through applicator, and specifically to a nib-type eyeliner pen. No further response to this argument has been provided. In addition, in the present specification at page 5, lines 13 to 15, the present invention is described as also including a flow-through nib-type pen and as having an added benefit of not clogging the wick of the pen. Therefore, Applicants maintain that the claims are commensurate in scope with the argument that the motivation to combine the references proposed by the Examiner does not exist because the '277 reference teaches away from the combination.

The Examiner refutes that the '277 reference teaches away from the combination because at column 1, lines 47 to 50 of the '277 reference it teaches that at a certain viscosity the '277 compositions will not cause clogging when used in a nib pen. However, Applicants point out that the '277 reference teaches water-soluble components in a water based system unlike that of the '072 reference. Thus, although the '277 water-based compositions may not clog a pen at a certain viscosity, what is of primary importance is that the '277 reference teaches and/or suggests that clogging will occur if, as the Examiner suggests, the '277 pigments are present in the '072 compositions, where the pigments will specifically be placed in the oil phase of the emulsion system. The pigments of the '072 reference are taught to be part of the solid portion present in the oil phase of the '072 compositions. Thus, Applicants' argument has been that the '277 reference teaches away from the combination of the cited references because the '277 reference, specifically at column 1, lines 22 to 31, teaches and clearly explains that oil causes clogging.

[N]ib pens have not been employed as a delivery system for lipliner because conventional lipliner compositions employ wax or anhydrous (oil) base which are

relatively viscous . . . and would therefore cause clogging of the wick.

One of ordinary skill in the art would not, therefore, combine the cited references because it would be expected that the oil present in the '072 compositions would cause clogging as taught by the '277 reference, and a *prima facie* case of obviousness is not made.

The benefit of the present invention, namely, that with respect to not clogging, in addition to the benefits with respect to not running and not bleeding, is described in the present specification at page 3, lines 12 to 13, and page 5, lines 13 to 15. The ability to overcome both of these challenges is achieved with the compositions of the present invention, and is not taught or suggested by the cited references, alone or in combination. The '072 reference fails to teach or suggest water soluble pigments, and the '277 reference fails to teach or suggest the polymeric component of the present invention. The aqueous based system of the present invention containing the water soluble pigment and the acrylic acid polymer is not taught by the combination of the cited references. The fact that this combination, namely, the water soluble pigment and the acrylic acid polymer, which is not taught or suggested by the cited references, achieves the benefits with respect to not clogging and not running are unexpected and surprising. Therefore, the method of combining these components is not obvious to one of ordinary skill in the art, contrary to the assertion made by the Examiner based on the fact that mixing inherently is a known processing step. The criticality of the method is not related to the act of mixing, *per se*, but rather on the act of mixing the nonobvious combination of the acrylic or methacrylic acid polymer and the water soluble pigment in an aqueous base, which is not taught or suggested by the cited references.

The Examiner also notes in the Advisory Action that Applicants argue that unexpected results have been achieved in response to the motivation the Examiner finds to combine the references, and therefore, that Applicants must comply with MPEP 706.02. However, in rejecting claims under 35 U.S.C. §103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Rijckaert*, 28 USPQ2d 1955, 1956 (CAFC 1993) (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992)). Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant. *Id.* "A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *Id.*, (citing *In re Bell*, 991 F.2d 781, 782, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) (quoting *In re Rinehart*, 531 F.2d 1048, 1051, 189 USPQ 143, 147 (CCPA 1976)). Since a *prima facie* case of obviousness has not been made, for reasons which are discussed above, the burden of coming forward with evidence or data regarding unexpected properties has not shifted to Applicants. Reference to unexpected results was Applicants' response to the Examiner's argument

regarding motivation to combine the references. Applicants merely note in the alternative that if, *arguendo*, a *prima facie* case of obviousness can be found, a specific combination can still be patentable even if it has already been recognized when there surprising or unexpected results. Thus, Applicants submit that the claims of the present application satisfy the requirements of 35 U.S.C. §103(a) because a *prima facie* case of obviousness has not been made, and Applicants request that the rejection under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Accordingly, the claims are believed to be in condition for allowance, and issuance of a Notice of Allowance is respectfully solicited.

Respectfully submitted,

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